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NOV 7 2012

Section 5. - 510(k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: August 31, 2012
Applicant: Solana Surgical, LLC
6363 Poplar Ave, Suite 434
Memphis, TN 38119
Phone: (901) 818-1860
Fax: (855) 540-1861
Contact: Rebecca Wahl

Common Name:	Subtalar Arthroereisis Implant
Device Trade Name:	Gaitway Implant System
Device Classification Name:	Smooth or threaded metallic bone fixation fastener.
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number:	21 CFR 888.3040
Product Code:	HWC
Predicate Devices:	K093820 Memometal SubFix Arthroereisis Implant K080280 Instratek, INC.Sub-Talar Lok, Model 7-11 mm K071456 Arthrex Pro Stop Plus

Device Description:

The Solana Surgical Gaitway Implant is a one-piece device made of Titanium Alloy intended to be implanted in the Sinus Tarsi of the foot. The implant is available in a range of sizes (5) ranging from 6.5 mm to 11.5 mm. The design of the Solana Surgical implant is similar to the predicate devices. No new materials or processes are used in the production of this implant.

Indications for use:

The Solana Surgical LLC, Gaitway Implant System is intended to treat the hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus blocking excessive pronation and the resulting sequela.

Summary Comparison to Predicate Devices:

The Solana Surgical device is similar to the Memometal Subfix™ Subtalar Arthroereisis Implant (K093820), the Instratek, Inc. Sub-Talar Lok, Model 7-11 mm (K080280) and the Arthrex Pro Stop Plus (K071456). Each device is placed into the sinus tarsi of the foot, allowing normal subtalar joint motion while blocking excessive pronation. The Memometal and Instratek devices are made of titanium alloy and the Arthrex device is made of Poly L – Lactide (PLLA). The Solana Surgical, Memometal, Instratek and Arthrex devices are conical in shape so as to fit into the anatomy of the sinus tarsi. Each system is cannulated to accept a guide wire for ease of

implantation. All devices are: intended for single use only; intended for surgical implantation longer than 30 days; are placed into the subtalar sinus tarsi.

Indications for use, geometry and material composition were considered in evaluating safety and effectiveness relative to predicate devices. The subject device is constructed of material that is identical to the Memometal and Instratek devices and greatly exceeds the mechanical strength characteristics of the Arthrex device. Given the similar geometry and equivalent or greater strength, the Solana Surgical device should not introduce new concerns of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter Dated: November 7, 2012

Solana Surgical, LLC
% Rebecca Wahl
Vice President Research and Development
6363 Poplar Ave. Suite 434
Memphis, Tennessee 38119

Re: K122738
Trade/Device Name: Gaitway Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 31, 2012
Received: September 6, 2012

Dear Ms. Wahl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122738
Device Name: Gaitway Implant System
Indications for Use:

The Solana Surgical LLC, Gaitway Implant System is intended to treat the hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus blocking excessive pronation and the resulting sequela.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122738